

Instructions for data entry manual for BIRAC registry database for solid tumors.

Section A: Demographics

- A.1. **Center:** Choose the center (TMH, ACTREC, BBCI, HBCH, WIA, MCC, MAX, NEIGRIHMS, RCC, CMC, and CCHRC) to which the admission has taken place
- A.2. **Case Number:** This is an alphanumeric unique filed and signifies original Medical Record Number/ Hospital Identity Number
- A.3. **First Name:** First name of the patient to be filled.
- A.4. **Middle Name:** Middle name of the patient to be filled.
- A.5. **Surname:** Last name of the patient to be filled.
- A.6. **DOB:** Specify the date of birth of the patient in dd-mm-yyyy format. If the exact birth date is not available then the year should be entered as 01-01-yyyy where yyyy is the year of birth.
- A.7. **Gender:** To enter male or female.
- A.8. **Permanent Address:** Local address details to be entered as:
 - a. **Flat/Building:** Enter the flat/ building number of the local address of the patient and his/her attendant where they are currently staying.
 - b. **Road:** Enter the road of the local address of the patient and his/her attendant where they are currently staying.
 - c. **Area:** Enter the area of the local address of the patient and his/her attendant where they are currently staying.
 - d. **City/District:** Enter the city/district of the local address of the patient and his/her attendant where they are currently staying.
 - e. **Pin code:** Enter the pin code of the local address of the patient and his/her attendant where they are currently staying.
 - f. **State:** Enter the state of the local address of the patient and his/her attendant where they are currently staying.
- A.9. **Mobile Number (self):** 10 digits mobile number of the patient to be filled.
- A.10. **Mobile Number (relative):** 10 digits mobile number of the attendant or any other closerelative of the patient to be filled. This field is not mandatory.
- A.11. **Landline:** 7 digits landline number with area code to be filled, if available. This field is not mandatory.
- A.12. **Aadhar:** 12 digits Aadhar number of the patient to be filled. This is a unique but non-mandatory field. Details of the Aadhar card will be extracted as per the requirement.
- A.13. **Cancer Site:** Site of cancer (Breast, Lung, Colon, Rectum or Others) to be selected.

Eligibility Check

Inclusion criteria:

1. All patients with confirmed diagnosis of lymphoma/chronic myeloid leukemia/ breast cancer/lung cancer/colorectal cancer who are being planned for treatment
2. Age >14 years
3. Willing for participation in the registry (the investigations, treatment and follow up will be as per the treating doctor and will be recorded from EMR).

Exclusion criteria:

1. Patients who have come only for second opinion
2. Patients who have been planned for best supportive care only

A.14. **Newly Diagnosed:** If the patient has been registered at your centre and diagnosed with cancer on or after 1st January 2021 then select “Yes” otherwise “No”. Please do not include those who have received treatment prior to registration at your centre or those with relapse.

A.15. **Will continue treatment at the center:** Specify whether the patient will continue further treatment at the center from Yes or No. This detail is to be specified by the clinicians.

A.16. **Second opinion:** Specify whether the patient has come to our center for a second opinion from Yes or No. This details is also to be specified by the clinicians.

If the above combination is “Yes-Yes-No”

A.17. **Patient ID:** Auto generated followed by center and cancer. Otherwise,
“The patient is not eligible for the study.”

Select the form status to be **complete** and then, if eligible click on “**Save and Next Form**”, else click on “**Save and Exit**”.

Section B: History

B.1. **First Evaluation Date:** Specify the date when the patient was registered at your Centre.

B.2. **Duration of Symptoms:** Duration of symptoms in years/ months/ weeks/ Not Known (NK) to be selected and then specify the duration. This information will be available in first evaluation in case notes by doctor or clinical notes

B.3. **Family history of cancer:** Yes/No/NK. If yes,

- a. **Relationship:** Relationship with the patient to be selected.
- b. **Site:** Site of cancer of the relative to be selected.

This information will be available in first evaluation any later evaluation in case notes by doctor or clinical notes

B.4. Past history of cancer: Site of the cancer that occurred in the past must be on other sites than the primary cancer site of consideration in present (e.g., - for a patient who is being registered in breast cancer database – prior history of breast cancer will not count in the past history. If that is the case then the patient is not eligible for entry in the registry) Yes/No/NK. If yes, specify:

- a. **Site of past cancer:** Site of the past cancer to be selected.
- b. **Age at diagnosis:** Age at diagnosis of past cancer to be filled.
- c. **Treatment:** Treatment given for the past cancer to be selected.

This information will be available in first evaluation any later evaluation in case notes by doctor or clinical notes

B.5. Comorbidities

a. **Any Comorbidity:** Yes/No/NK. If yes, specify:

- i. **Name of comorbidities:** Comorbidities can be selected from the first evaluation page. Ex: Diabetes, Hypertension.

This information will be available in first evaluation any later evaluation in case notes by doctor or clinical notes

B.6. Habits

B.6.a.Smoker: Specify whether the patient is smoker or not from Yes or No. If yes, specify:

- i. **Smoker:** Specify whether the patient is an ex-smoker or current smoker.
- i. **Duration:** Specify the duration of smoking habit.

B.6.b. Smokeless tobacco: Yes/No/NK. If yes, specify:

- i. **Types of smokeless tobacco:** Types of smokeless tobacco consumed to be selected (pan masala, masher, gutkha, others). If others, specify_____.
- ii. **Duration:** Specify the duration of smokeless tobacco consumed.

B.6.c.Alcohol: Yes/No/NK. If yes, specify:

- i. **Duration:** Specify the duration for which the patient has been consuming alcohol. This question is specific to lung cancer site only.
- ii. **Alcohol Consumption:** Specify whether the patient is Ex-alcoholic/current alcoholic.

This information will be available in first evaluation any later evaluation in case notes by doctor or clinical notes

Select the form status to be **complete** and then click on “**Save and Next Form**”.

Section C: Examination

Kindly refer to the respective annexure for additional site-specific fields.

Performance Status: Performance status abbreviated as PS is a score that estimates the patient's ability to perform certain activities of daily living (ADLs) without the help of others. The values are 0, 1, 2, 3, 4 and NK. It is also represented by ECOG (Eastern Cooperative Oncology Group) or KPS (Karnofsky Performance Status). This information will be available in first evaluation in case notes by doctor or clinical notes

C.1. **Primary site of cancer:** Auto generated.

Laterality/subsite (site-specific field): Laterality/subsite (left /right or others) describes the exact location in the chosen primary cancer site of cancer. This information will be available in in case notes by doctor or clinical notes or in joint clinic notes or pathology reports.

C.2. **Blood Investigations:** Specify whether blood investigations have been done or not done. If done, specify the following investigations values and their units from the dropdown. If the unit is not in the list, select other and kindly specify your unit.

Note: All the blood investigations information should be collected from the “lab reports” of the tests done within 3 to 4 weeks from the date of registration. However, it must be before the start of treatment that is chemotherapy, surgery or radiation.


- i. **Hb** (g/dl): Hemoglobin abbreviated as Hb is the part of the red blood cell (RBC) that carries oxygen to all the cells in your body. Its values lie between 1-22 g/dl and are available from the haematopathology laboratory (HL) reports.
- ii. **TLC** ($\times 10^9/l$): Total Leukocyte Count/total WBC is abbreviated as TLC. Its values lie between 1-50 $\times 10^9/l$ and is available from the haematopathology laboratory (HL) reports.
- iii. **Platelets** ($\times 10^9/l$): Platelets are a part of blood that helps in its clotting. It is available from the haematopathology laboratory (HL) reports.
- iv. **ANC** ($\times 10^9/l$): Absolute Neutrophil Count is abbreviated as ANC. Its value lies between 2.0-7.0 $\times 10^9/l$ and is available from the haematopathology laboratory (HL) reports.
- v. **Creatinine** (mg/dl): Its unit is mg/dl and is available from the biochemistry or renal function test (laboratory reports)
- vi. **Albumin** (g/dl): Its unit is g/dl and is available from the biochemistry laboratory (liver function test) reports.

- vii. **SGOT** (units/l): Serum Glutamic Oxaloacetic Transaminase abbreviated as SGOT. It is measured in units per litre and is available from the biochemistry laboratory (liver function test) reports.
- viii. **SGPT**- (units/l): Serum Glutamic Pyruvic Transaminase abbreviated as SGPT. It is measured in units per litre and is available from the biochemistry laboratory (liver function test) reports.
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- ix. **Bilirubin-direct** (mg/dl): Its unit is mg/dl and is available from the biochemistry laboratory (liver function test) reports.
- x. **Bilirubin-total** (mg/dl): Its unit is mg/dl and is available from the biochemistry laboratory (liver function test) reports.
- xi. **SAP** (units/l): Serum Alkaline Phosphatase abbreviated as SAP. It is measured in units per liter and is available from the biochemistry laboratory (liver function test) reports.

Select the form status to be **complete** and then click on “**Save and Next Form**”.

Section D: Histopathology

Kindly refer to the respective annexure for additional site-specific fields.

(The color-coded  section in this instrument needs to be verified by the Co-Investigator)

Note: All the histopathology information should be collected from the Surgical Pathology laboratory reports (biopsy report) of the tests done within 6 weeks from the date of registration. However, before the start of treatment that is chemotherapy, surgery or radiation.

This is different from the pathology reports which comes after the surgery is done.

D.1. Histopathology on biopsy however, before the start of treatment

- a. **Histopathology (site-specific field):** Select the histopathology’s specific to the cancer site. Multiple options can also be selected.
- b. **Grade:** It states the grade of the cancer cells. It must be represented as I, II, III, IV, Not Available (NA) and NK.
- c. **Differentiation:** It states how well the cancer cells are differentiated. It can be well, moderate, poor, NA or NK.

d. **Date of biopsy report***: This represents the date when the biopsy from the primary cancer site was done. This will be mentioned on the pathology report itself.

***Do not write Registration date.**

D.2. Tumour markers/ Hormone:

***All the values of tumour markers can be found from the tumour marker test reports done within 6 weeks from the date of registration and prior to start of treatment that is chemotherapy, surgery or radiation.**

- a. **AFP** (ng/ml): Alpha-fetoprotein abbreviated as AFP is a protein that in humans is encoded by the AFP gene. Its unit is ng/dl.
- b. **βhCG** (mIU/ml): Human chorionic gonadotropin (hCG) is often called beta hCG (βhCG) and is measured in mIU/ml.
- c. **LDH** (U/L): Lactate dehydrogenase abbreviated as LDH is a protein that is measured in units/l.
- d. **CEA** (ng/ml): Carcinoembryonic antigen (CEA) describes a set of highly related glycoproteins involved in cell adhesion. CEA is normally produced in gastrointestinal tissue during fetal development. Its unit is ng/ml.
- e. **CA 19.9** (units/ml): Carbohydrate antigen 19-9, also known as sialyl-Lewis^A, is a tetrasaccharide which is usually attached to O-glycans on the surface of cells. It is measured in units/ml.
- f. **CA 15.3**(units/ml): CA 15-3, for Carcinoma Antigen 15-3, is a tumor marker notably for breast cancer and is measured in units/ml.
- g. **CA 125** (units/ml): CA-125 also known as mucin 16 or MUC16 is a protein that in humans is encoded by the MUC16 gene. It is measured in units/ml.
- h. **PSA** (ng/ml): Prostate-specific antigen (PSA) is the most important tumor marker for prostate cancer. It is measured in ng/ml.
- i. **Metanephrine** (pg/ml): Plasma Metanephrines are Markers of Pheochromocytoma Produced by Catechol-O-Methyltransferase within tumors and is measured in pg/ml.
- j. **Nor-Metanephrine** (pg/ml): Nor-metanephrine is a metabolite of norepinephrine created by action of catechol-O-methyl transferase on norepinephrine that is excreted in the urine It is a marker for catecholamine-secreting tumors such as pheochromocytoma and is measured in pg/ml.
- k. **PTH** (pg/ml): Parathyroid hormones (PTH) are measured in pg/ml.
- l. **TSH** (uIU/ml): Thyroid stimulating hormone (TSH) is a marker for thyroid cancer and is measured in uIU/ml.
- m. **ACTH** (pg/ml): Adrenocorticotrophic hormone (ACTH) is a polypeptide hormone produced by the corticotrophic cells of the anterior pituitary gland and is measured in pg/ml.

- n. **Cortisol** (mcg/ml): Cortisol as a possible marker of metastatic adrenocortical and is measured in mcg/ml.
- o. **FSH** (mIU/ml): Follicular stimulating hormone (FSH) is measured in mIU/ml.
- p. **LH** (IU/l): Lutenizing hormone (LH) is measured in IU/l.

D.3. **Radiological test done for staging:** Select the radiological tests done from the multiple choices available. This can be CT, USG, PET-CT, MRI. These are tests which are done before start of therapy that is chemotherapy, surgery or radiation.

D.4. Clinical stage of tumour after radiological evaluation

- a. **Clinical stage of tumour:** Stage refers to the extent of cancer, such as how large the tumor is, and if it has spread. There are 3 stages of cancer T, N and M. T has subtypes T0, T1, T2, T3, T4. N has subtypes N0, N1, N2, N3. M has subtypes M0, M1 and is available from clinical evaluation or case notes or joint clinic notes.

***If M stage of Clinical Stage of Tumour is M1, then metastatic disease is present.**

If metastatic diseases present: Select the site of metastatic disease. This can be found in the CT scan or PET scan report and in clinical notes. Typical metastatic sites are bone, lung (opposite lung in patients with lung cancer), liver, brain.

- b. **Tumour size:** Specify the largest dimension of tumour size of radiology in decimal format. It would be available from MRI/PET-CT/CT/Mammogram imaging report.
- c. **Immunohistochemistry:** Immunohistochemistry abbreviated as IHC is a method that uses antibodies to check for certain antigens in a sample of tissue and is available from Specimen Biopsy report/slide blocks report or surgical specimen report The available options are Biopsy, Surgical Specimen and Both.
- d. **IHC:** Select IHC according to cancer specific site. Also, select Positive/Negative/NK for the selected IHCs. NK means it is not done.

Select the form status to be **complete** and then click on “**Save and Next Form**”.

Section E: Treatment Plan

Kindly refer to the respective annexure for additional site-specific fields.

(The color-coded section in this instrument needs to be verified by the Co-Investigator)

Note: All the treatment plan related information should be collected from the “Patient’s”

clinicalevaluation notes/ case notes or joint clinic notes” before the actual start of treatment.

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All the treatment given related information should be collected from the “Clinical Notes, surgery notes, radiation summary notes, prescriptions”. Please note that a patient may have been planned for treatment but may not receive it. So, enter both planned and given treatment.

E.1. Treatment plan and intent: Specify the type of treatment to be given to the patient whether it is curative, palliative or NA if that information is not available

Curative care is defined as the care aims to cure disease and is mostly for patients who do not have metastatic disease. Palliative intent is for metastatic disease or patients who are in poor general condition.

Planned treatment: Specify whether the treatment for the patient is planned or not from yes, no and NA. If yes, specify: If the information on plan of treatment is not available then select NA.

E.2. Surgery: Specify whether surgery is planned from yes, no, NK, and NA. If yes, specify.

If the information on plan of treatment is not available then select NA.

Treatment Given:

- i. **Surgery given:** Specify whether surgery was given as a treatment to the patient from yes or no. If yes, specify. This can be found in clinical notes or OT notes
- ii. **Surgery name:** Specify the type of surgery given. This can be found in clinical notes or OT notes
- iii. **Date of surgery:** This specifies the date when the surgery of primary tumour was done for a particular patient. This can be found in clinical notes or OT notes
- iv. **Surgical Complications - Clavien Dindo Classification:** Mention the Clavien Dindo classification grade of the surgical complications.

It would be mentioned in clinical notes or surgical reports.

Note: All the surgery related information should be collected from the “Surgery reports” done within 3 weeks to 8 months from the date of registration.

E.3. Radiation: Specify whether radiation therapy is planned or not from yes, no and NA. If yes, specify

#Note: All the radiation related information should be collected from the “Radiotherapy Prescription Paper OR Radiotherapy Summary Reports” done within 3 weeks to 8 months from the date of registration.

Treatment Planned:

- i. **Radiation type:** Specify the type of radiation therapy that is planned to be given to the patient from neoadjuvant, adjuvant, definitive, concurrent or palliative^{##}.

Neoadjuvant treatment is the treatment that is administered before the primary treatment to enhance the outcome of the primary treatment.

Adjuvant treatment is the treatment that is applied after the primary treatment especially to suppress secondary tumour formation.

Definitive/Primary treatment is the treatment plan that has been chosen as the best one specific to the patient after all other choices have been considered.

Concurrent treatment specifies the use of two treatments at the same time (for eg.; chemotherapy administered along with radiation therapy).

Palliative treatment is an approach that improves the quality of life of patients and their families who are facing problems associated with cancer.

This information will be in clinical notes or radiation oncology notes or in joint clinic notes

Treatment Given:

- ii. **Radiation given:** Specify whether radiation therapy was given as a treatment to the patient from yes or no. If yes, specify
- iii. **Radiation type:** Specify the type of radiation therapy that is given to the patient from neoadjuvant, adjuvant, definitive, concurrent or palliative.
- iv. **Radiation dose and fractions (site-specific field):** Select the radiation dose and its fractions based on the type of radiation given.
- v. **Start date:** This specifies the date when the specific radiation treatment was started.
- vi. **Stop Date:** This specifies the date when the specific radiation treatment was stopped.

This information will be in clinical notes or radiation oncology notes or in joint clinic notes

- E.4. **Chemotherapy:** Specify whether chemotherapy is planned or not from yes, no and NA. If yes, specify

Note: All the chemotherapy related information should be collected from clinical notes, joint clinic or from prescriptions from 3 weeks after registration to 10 months .

Treatment Planned:

- i. **Chemotherapy type:** Specify the type of chemotherapy that is planned to be given to the patient from neoadjuvant, adjuvant, maintenance or palliative.

Maintenance treatment is given to help keep cancer from coming back after it has disappeared following the initial therapy. It may include treatment with drugs, vaccines, or antibodies that kill cancer cells, and it may be given for a long time.

Treatment Given:

- ii. **Chemotherapy given:** Specify whether chemotherapy was given as a treatment to the patient from yes or no. If yes, specify
- iii. **Chemotherapy type:** Specify the type of chemotherapy that was given to the patient from neoadjuvant, adjuvant, maintenance, or palliative.
- iv. **Drugs:** Specify the drugs given for the chemotherapy given according to each of the chemotherapy type given.
- v. **Cycles:** State the number of cycles of chemotherapy given to the patient.
- vi. **Start date:** This specifies the date when the specific chemotherapy treatment was started.
- vii. **Stop Date:** This specifies the date when the specific chemotherapy treatment was stopped.

Note: All the chemotherapy related information should be collected from clinical notes, joint clinic or from prescriptions from 3 weeks after registration to 10 months .

- E.5. **Targeted therapy:** Specify whether targeted therapy is planned or not from yes, no and NA. If yes, specify

Note: All the targeted therapy related information should be collected from clinical notes, joint clinic or from prescriptions from 3 weeks after registration to 10 months .

Treatment Planned:

- i. **Targeted therapy type:** Specify the type of targeted therapy that is planned to be given to the patient from neoadjuvant, adjuvant, maintenance, or palliative.

Treatment Given:

- ii. **Targeted therapy given:** Specify whether targeted therapy was given as a treatment to the patient from yes or no. If yes, specify
- iii. **Targeted therapy type:** Specify the type of targeted therapy that was given to the patient from neoadjuvant, adjuvant, maintenance, or palliative.
- iv. **Drugs:** Specify the drugs given for the targeted therapy given according to each of the targeted therapy type given.
- v. **Cycles:** State the number of cycles of targeted therapy given to the patient.
- vi. **Start date:** This specifies the date when the specific targeted therapy was started.
- vii. **Stop Date:** This specifies the date when the specific targeted therapy was stopped.

Note: All the targeted therapy related information should be collected from clinical notes, joint clinic or from prescriptions from 3 weeks after registration to 10 months.

- E.6. **Hormone therapy (site specific field):** Specify whether hormone therapy is planned or not from yes, no and NA. If yes, specify

Note: All the hormone therapy related information should be collected from clinical notes, joint clinic or from prescriptions from 3 weeks after registration to 12 months.

Treatment Planned:

i. **Hormone therapy type:** Specify the type of hormone therapy that is planned to be given to the patient from neoadjuvant, adjuvant, maintenance, or palliative.

Treatment Given:

ii. **Hormone therapy given:** Specify whether hormone therapy was given as a treatment to the patient from yes or no. If yes, specify

iii. **Hormone therapy type:** Specify the type of hormone therapy that was given to the patient from neoadjuvant, adjuvant, maintenance, or palliative.

iv. **Drugs:** Specify the drugs given for the hormone therapy according to the hormone therapy type given.

v. **Start date:** This specifies the date when the hormone therapy was started.

vi. **Stop Date:** This specifies the date when the hormone therapy was stopped.

Select the form status to be **complete** and then click on “**Save and Next Form**”.

Section F: Follow-up

(The color-coded section in this instrument needs to be verified by the Co-Investigator)

Note: All the follow-up related information should be collected from the Clinical notes or “Clinical Investigations Reports” after the treatment completion.

F.1. **Follow-up visit number:** Follow-up visit number to be specified

F.2. **Date of last follow-up:** Specify the date of last follow-up in dd-mm-yyyy format.

F.3. **Has the patient experienced, cancer relapse or progression:** Yes / No / NA / NK. If yes, specify

a. **Date of relapse/ progression:** Specify the date of relapse/progression in dd-mm-yyyy format.

b. **Site of relapse/ progression:** Site of relapse/ progression to be filled.

F.4. **Any salvage therapy given:** Yes / No / NA / NK. If yes, specify

a. **Type of salvage therapy:** Type of salvage therapy to be filled.

Salvage therapy: The treatment that is given after the cancer has not responded to the standard therapy or the treatment given when patient has experienced relapse or progressive disease.

F.5. **Patient Status:** Alive / Dead. If dead, specify

a. **Date of death:** Specify the date of death in dd-mm-yyyy format.

b. **Cause of death:** Select the appropriate cause of death.

F.6. **Form filled by:** Enter the name of the person who has filled the current CRF.

Select the form status to be **complete** and then

a. To update the follow-up details, select “**Save & Go to Next Instance**”.

b. To enter details of another patient click on “**Save and Next Record**”

Else,

c. Click on “**Save and Exit**”.

Section G: Toxicity

Note: All the toxicity related information should be collected from the “Patient’s clinical evaluation paper”.

Date of occurrence: Please mention the date of occurrence of a particular toxicity into consideration.

Mark the category of toxicity considering and identifying during which cancer therapy the specific toxicity has occurred.

Toxicity is divided into two categories:

A. Haematological Toxicity: Toxicity which is related to blood counts are termed as haematological toxicities. These are neutropenia, anaemia, thrombocytopenia, febrile neutropenia, etc.

B. Non-haematological toxicities: Toxicities other than blood counts are called as non-haematological toxicities. These are vomiting, mucositis, diarrhoea, etc.

Note: This registry will record only grade 3 and grade 4 toxicities. Also mention during which phase of treatment or setting has the toxicity occurred.

The toxicities recorded in this registry are segregated according to therapy and phase of the treatment.

Therapy: Chemotherapy, targeted chemotherapy, radiation therapy.

Phase/setting: Neoadjuvant, adjuvant, concurrent, maintenance, palliative.

ANNEXURE.1. BREAST

Section C: Examination

Laterality: Select the exact location where the tumor is situated [right/left/bilateral (both)].

Section D: Histopathology

***If laterality is selected as bilateral in the examinations section then enter all the information in the further sections of the registry for both left and right laterality.**

D1. Histopathology on biopsy: Select the histopathology for the tumor amongst the given options in the database. This information should be collected from the biopsy report. You may select multiple options in case tumor shows mixed histopathology.

- e. **Date of biopsy:** This specifies the date of biopsy.
- f. **Tumour size:** Specify the largest dimension of tumour size available after radiological evaluation. This information will be available in CT/MRI/PETCT reports.
- g. **Any In situ focus:** A group of abnormal cells that remain in the place where they first formed. The values are Yes, No, NA, NK and are available from Specimen Biopsy report.
- h. **Nodes dissected:** A surgical procedure in which the nodes are removed and a sample of tissue is checked under a microscope for signs of cancer. The values are Yes, No, NA, NK and are available from Specimen Biopsy report. If yes, specify
- i. **Number of nodes dissected:** Number of nodes dissected to be filled
- j. **Number of nodes positive:** Select the number of nodes that are positive out of the dissected nodes.

Number of nodes positive are usually less than number of nodes dissected.

Section E: Treatment Plan

E.7. **Hormone therapy:** Specify whether hormone therapy is planned or not from yes, no and NK. If yes, specify

Note: All the hormone therapy related information should be collected from clinical notes, joint clinic or from prescriptions from 3 weeks after registration to 12 months.

Treatment Planned:

- i. **Hormone therapy type:** Specify the type of hormone therapy that is planned to be given to the patient from neoadjuvant, adjuvant, maintenance, or palliative.

Treatment Given:

- ii. **Hormone therapy given:** Specify whether hormone therapy was given as a treatment to the patient from yes or no. If yes, specify
- iii. **Hormone therapy type:** Specify the type of hormone therapy that was given to the patient from neoadjuvant, adjuvant, maintenance, or palliative.
- iv. **Drugs:** Specify the drugs given for the hormone therapy according to the hormone therapy type given.
- v. **Start date:** This specifies the date when the hormone therapy was started.
- vi. **Stop Date:** This specifies the date when the hormone therapy was stopped.

ANNEXURE.2. COLON

Section C: Examination

C.2 Subsite: Choose from the given choices.

C.7 Colonoscopy:

- i. **Number of lesions (s):** Add the number of lesions in the textbox. This should be collected from colonoscopy report.
- ii. **Polyps:** Choose whether polyps are reported to be present or not as Yes or No, If yes specify number of polyps.

Section D: Histopathology

- a. **Proximal margin length:** Fill the details in the textbox in centimeters.
- b. **Distal margin length:** Fill the details in the textbox in centimeters.
- c. **Circumferential margin length:** Fill the details in the textbox in centimeters.
- d. **Lymphovascular invasion (LVI):** Mention the presence of LVI as Yes, No and NK.
- e. **Tumor budding:** Mention the presence of tumour budding as Yes, No and NK.
- f. **Perinodal extension:** Mention the presence of tumour budding as Yes, No and NK.

All the above information should be collected from the final surgical specimen histopathology report.

Section G: Treatment Plan

- a. If surgery is performed, mention the name of primary surgery. Select from the list given. Multiple options can be selected.

- b. If the cancer is metastatic, mention the site of metastases.
- c. Complications of surgery:
 - 1. In case stoma is reported, mention if stoma is temporary or permanent.
 - 2. Mention if leak is noticed in the form of Yes and No.
 - 3. Mention if 30 days mortality (death date within 30 days of surgery date) has occurred in the form of Yes and No.
 - d. Radiation treatment doesn't exist in the colon cancer treatment.

ANNEXURE.3. RECTUM

Section C: Examination

C.1. **Subsite:** Choose from the given choices.

C.7 Colonoscopy:

- i. **Number of lesions (s):** Add the number of lesions in the textbox. This should be collected from colonoscopy report.
- ii. **Polyps:** Choose whether polyps are reported to be present or not as Yes or No, If yes specify number of polyps.
- iii. **Colonoscopic Obstruction:** Choose whether colonoscopic obstruction is reported to be present or not as Yes or No

C. 8 MRI Pelvis:

- i. **Distance from anal verge (mm):**
- ii. **T stage:** Choose from the given choices.
- iii. **Mesorectal Facia (MRF):** Choose the involvement of mesorectal facia as positive or negative.
- iv. **Mesorectal nodes:** Choose whether the involvement mesorectal nodes as yes, no and NK.
- v. **Lateral pelvic lymph node:** Choose whether the involvement lateral pelvic nodes as yes, no and NK.
- vi. **Extra pelvic node:** Choose whether the involvement extra pelvic nodes as yes, no and NK.
- vii. **Extramular vascular invasion:** Mention the presence of extramular vascular invasion as Yes, No and NK.

Section D: Histopathology

- a. **Proximal margin length:** Fill the details in the textbox in centimeters.
- b. **Distal margin length:** Fill the details in the textbox in centimeters.
- c. **Circumferential margin length:** Fill the details in the textbox in centimeters.

- d. **Lymphovascular invasion (LVI):** Mention the presence of LVI as Yes, No and NK.
- e. **Tumor budding:** Mention the presence of tumour budding as Yes, No and NK.
- f. **Perinodal extension:** Mention the presence of tumour budding as Yes, No and NK.

All the above information should be collected from the final surgical specimen histopathology report.

Section G: Treatment Plan

- a. If surgery is performed, mention the name of primary surgery. Select from the list given. Multiple options can be selected.
- b. If the cancer is metastatic, mention the site of metastases.
- c. Complications of surgery:
 - 1. In case stoma is reported, mention if stoma is temporary or permanent.
 - 2. Mention if leak is noticed in the form of Yes and No.
 - 3. Mention if 30 days mortality (death date within 30 days of surgery date) has occurred in the form of Yes and No.